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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,630	06/29/2005	Bernd Bufe	BB-138	7026

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,630	BUFE ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9,12 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9,12 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1) Claims 1 to 5, 7, 9, 12 and 14 to 19 are pending in the instant application. Claims 1 to 3, 5, 7, 9, 12, 14, 15 and 19 have been amended and claims 6, 10, 11, 13, 21 and 24 have been canceled as requested by Applicant in the correspondence filed 23 April of 2007.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

4) The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 112

5) Claims 1 to 5, 7, 9, 12 and 14 to 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims encompass a binding assay that can employ a nucleic acid encoding a polypeptide having bitter substance binding activity wherein that polypeptide comprises other than the entire amino acid sequence presented in SEQ ID NO:1 of the instant application. Section (c) of claim 14, for example, encompasses a process that employs a polypeptide having absolutely no sequence identity to SEQ ID NO:1 of the instant application. It is well settled in the art of molecular genetics that a single amino acid residue is encoded by three consecutive nucleotide bases and that those three bases constitute a codon. It is also well settled that the change of only base in a codon can be sufficient to change the amino acid residue encoded thereby. A change of 33% of the bases in the peptide coding region of a nucleotide sequence can change every amino acid residue encoded by that sequence. Therefore, a first nucleotide sequence having as much as 67% identity to SEQ ID NO:2 of the instant application can encode a protein having no amino acid sequence similarity to SEQ ID NO:1. The instant specification fails to describe a polypeptide having anything less than the entire, unaltered amino acid sequence presented in SEQ ID NO:1, wherein that polypeptide possesses bitter substance binding activity

Further, the instant specification does not provide the guidance needed to practice the claimed process with a polypeptide comprising anything less than the entire amino acid sequence presented in SEQ ID NO1. The only manner described in the instant specification of using the claimed method, and the polypeptide and polynucleotide employed therein, is in the identification of compounds that have potential use because of their ability to agonize or antagonize the human taste receptor

protein described therein. The invention is only useful in so far as the claimed protein protein employed in the claimed assay responds in a manner that is predictive of an authentic physiological response. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics **predicted** by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

One of ordinary skill in the art of receptor biology would not reasonably believe that the majority of physical peptide embodiments encoded by a nucleotide sequence having at least 50% sequence identity to SEQ ID NO:2 are going to be functional, much less be capable of producing an authentic response. Because the instant specification does not identify those amino acid residues in SEQ ID NO:1 which are critical to the structural and functional integrity of a bitter taste receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified taste receptor protein of the instant invention, an artisan can

not change even a single residue within the amino acid sequence of SEQ ID NO:1 and predict the effects of that change on the performance of that protein "by resort to known scientific law". Unless one can predict, with reasonable confidence, that an intentionally modified taste receptor protein is going to produce a response that is predictive of a native human bitter taste receptor protein, the information obtained from a process that uses that modified protein is of no practical value.

Further, claim 12 is neither enabled nor adequately described because there is absolutely no evidence of record to support an assertion that the exogenous administration of a polypeptide corresponding to one of the four extracellular domains from a taste receptor protein will in any way antagonize or inhibit the natural activity of the receptor protein from which that polypeptide was derived. The "extracellular domain" of SEQ ID NO:1 consists of four discontinuous sequences corresponding to an amino terminus and three extracellular loops. The instant specification does not describe even a single working example of an antagonistic polypeptide comprising any one or more of those discontinuous sequences nor does it identify any publications that were available at the time that the application was filed which described an antagonistic polypeptide that was derive from any member of the G protein-coupled receptor family and, in particular, a G protein-coupled sensory receptor such as a taste or odorant receptor. In addition, there is no evidence or sound scientific reason of record that supports a conclusion that a polypeptide comprising any one or more of those four discontinuous is capable of binding to a bitter substance outside of the context of the receptor protein in which that sequence is naturally found. A patent is granted for a completed invention,

not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and produce the claimed antagonistic polypeptide without first making a substantial inventive contribution.

6) Claims 1 to 5, 7, 9, 12 and 14 to 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 5, 7, 9, 12, 14, 15 and 19 are vague and indefinite because the recitation of "a deduced amino acid sequence as shown in SEQ ID NO:1" implies that there is more than one amino acid sequence presented in SEQ ID NO:1. The original language "the deduced amino acid sequence as shown in SEQ ID NO:2" was not vague and indefinite because of the "the" but because there is no amino acid sequence in SEQ ID NO:2. These claims are vague and indefinite because the phrase "a coding sequence, as shown in SEQ ID NO:2" implies that there is more than one coding

sequence in SEQ ID NO:2. These claims are vague and indefinite because there is no antecedent basis for "the polypeptide" referred to in section "(b)".

Claims 2, 4 and 16 to 18 are vague and indefinite in so far as they depend from any one of claims 1, 3, 5, 7, 9, 12, 14, 15 for those elements cited above.

Claim Rejections - 35 USC § 102

7) Claims 1 to 5, 7, 9 and 14 to 19 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Adler publication (WO 01/77676 A1).

8) Claims 1 to 5, 7, 9 and 14 to 19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Adler patent publication US 20020094551 A1),

As stated in the previous office action, the nucleotide sequence presented in SEQ ID NO:2 of the instant application is 99.8% identical to the sequence presented in SEQ ID NO:1 of each of the Adler patent documents (WO 01/77676 A1, US 20020094551 A1), which described that sequence as encoding a bitter taste receptor.

Conclusion

9) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOHN ULM
PRIMARY EXAMINER
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